HHS SBIR PAR-13-250

NOTE: The Solicitations and topics listed on this site are copies from the various SBIR agency solicitations and are not necessarily the latest and most up-to-date. For this reason, you should use the agency link listed below which will take you directly to the appropriate agency server where you can read the official version of this solicitation and download the appropriate forms and rules.

The official link for this solicitation is: http://grants.nih.gov/grants/guide/pa-files/PAR-13-250.html

Agency:
Department of Health and Human Services

Release Date:
June 24, 2013
Branch:
n/a

Open Date:
June 24, 2013
Program / Phase / Year:
SBIR / Phase II / 2013

Application Due Date:
September 11, 2015
January 13, 2016
May 13, 2016

Solicitation:
PAR-13-250

Close Date:
May 13, 2016 (closing in 194 days)
Topic Number:
PAR-13-250

Description:
Purpose

This Funding Opportunity Announcement (FOA) invites Small Business Innovation Research (SBIR) grant applications from small business concerns (SBCs) that propose to implement investigator-initiated clinical trials.

A clinical trial is defined by NIH as: “A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective.”

This program will utilize the cooperative agreement mechanism (U44) to enable support for milestone-driven, hypothesis-driven clinical trials related to the research mission of the NIAID that address a research area considered high priority by the Institute. This FOA will accept both SBIR Phase II and Fast-Track (Phase I/Phase II) applications. Applicants seeking only SBIR Phase II support must have received SBIR Phase I support that is appropriate and relevant (e.g., pre-clinical studies, planning activities, etc.) to this FOA.

Although clinical trials not considered high-risk (see NOT-AI-10-024) may be proposed, this program encourages high-risk clinical studies. High-risk does not imply human subject or patient risk, but rather defines a study that contains one or more of the following unique attributes: involves non-routine interventions, administration of an unlicensed product, or administration of a licensed product for an unapproved indication. Additionally, mechanistic studies are encouraged and can be proposed under this program. Applicants may not propose more than one clinical trial per application.

The NIAID has a robust infrastructure for conducting clinical studies that includes independently managed resources provided through grants and contracts, as well as resources that are integrated within existing NIAID-supported clinical trial networks. Proposed clinical trials may use NIAID's independent infrastructure for clinical studies; however, support will not be provided for studies that propose to use dedicated resources that are part of a NIAID-supported clinical trial network.

Background

Over the past three years, the NIAID has committed over $2 billion to clinical research, of which $1.5 billion has been devoted to clinical trials. Clinical trials are one strategy the NIAID uses to improve the understanding of the clinical mechanisms of infectious, immunologic, and allergic diseases or to improve prevention, diagnosis, and treatment. For additional information about the mission, strategic plan, and research interests of the NIAID, applicants are encouraged to consult the NIAID Planning and Priorities web site.

Clinical Trial Infrastructure

Historically, the NIAID has supported a wide variety of clinical research activities through clinical trial networks funded through cooperative agreements, solicited under NIAID Requests for Applications (RFAs), and solicited under NIAID Requests for Proposals (RFPs). These networks focus on high-priority disease research areas. Examples include the HIV/AIDS Clinical Trial Networks supported by the Division of AIDS, the Division of Microbiology and Infectious Diseases Clinical Trials Programs and Networks, and the Immune Tolerance Network supported by the Division of Allergy, Immunology and Transplantation.

In addition, NIAID's clinical research infrastructure includes independently managed coordinating centers, statistical units, data centers, central laboratories, clinical centers, and other specialized resources. For additional information on NIAID supported clinical research resources refer to the Preclinical and Clinical Research Resources page.

Investigator-Initiated Clinical Trials

Although clinical trial infrastructure is crucial to furthering the Institute's research, the NIAID recognizes that additional means to support clinical research may be important to advancing its research mission. Therefore, the NIAID has established the investigator-initiated clinical trial program for clinical trials that cannot or will not be conducted through existing NIAID-supported clinical trial networks. This FOA supports applications that propose clinical trials to be conducted outside of NIAID's existing clinical trial infrastructure; support will not be provided for clinical trials that propose to use dedicated resources that are part of a NIAID-supported clinical trial network.

This FOA provides a unique and focused opportunity for small business concerns (SBCs) interested in conducting clinical trials. If a clinical trial is ready for implementation, and readiness is adequately supported by appropriate documentation, SBCs are encouraged to submit applications to this FOA.

For additional information about NIAID's investigator-initiated clinical trial program, see the Investigator-Initiated Clinical Trial Resources Page.

Scope of the Program

The NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44) program supports implementation of clinical trials from small business concerns (SBCs) that propose clinical trials in research areas that are well matched with the mission and goals of the NIAID.

The proposed clinical trial should be hypothesis-driven and milestone-driven. Clear primary and secondary endpoints should be identified, including a description of the study population, justification for selecting the study group to address the research question(s) posed, subject eligibility, inclusion and exclusion criteria, and a feasible recruitment and enrollment plan. Statistical methods appropriate for the study design, and adequate plans for data monitoring and safety should be included.

All clinical trial planning activities must be completed prior to the time of application submission and all requested documentation needs to be provided for an application to be considered complete.

Investigators are referred to NIAID's Clinical Research Toolkit website for protocol templates and guidance, clinical research resources, and links to program divisions. Investigators are strongly encouraged to contact the NIAID Scientific/Research Contact(s) for information regarding division-specific clinical research policies and procedures.

This program will support implementation of proposed clinical trials not considered high-risk. However, applicants are encouraged to propose high-risk clinical trials. A high-risk clinical trial as defined by the NIAID (NOT-AI-10-024) does not imply human subject or patient risk, but rather defines a study as having one or more of the following attributes:

- provision of a non-routine intervention, that is, an intervention or non-routine use of an intervention that would not otherwise be provided for the condition under study in the local facility where the study is being conducted;
- administration of an unlicensed product; or
- administration of a licensed product for an unapproved indication.

For the purposes of this FOA, implementation support is defined as support for the conduct, completion, and analysis of a clinical trial, including activities related to the conduct of the clinical trial, which include but are not limited to the following:

- training of study personnel;
- enrollment and recruitment of study subjects;
- investigational product costs;
- data collection, management and quality control;
- laboratory work and data analyses;
- study management and oversight;
- establishment of committees to manage the complexity of the trial;
- preparation of the final study report; and
- other related post-enrollment activities.

Milestones

Delineation of milestones is a key characteristic of awards made in support of the NIAID's investigator-initiated clinical trial program, including this NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44) FOA. A milestone is defined as a scheduled event in the project timeline, signifying the completion of a major project stage or activity.

Proposed clinical trial milestones provide a clear delineation of the criteria used to identify completed activities, but also provide for contingency plans to accommodate anticipated impediments that could require a revision in the timeline. Recognizing and indicating potential problems and obstacles are important aspects in identifying and discussing alternative approaches. The milestones will undergo peer review and will be incorporated into the terms of award.

Commercialization Plan

Applications must include a Commercialization Plan (see SF424 (R&R) SBIR/STTR Application Guide) that provides a strategy for promoting further commercialization beyond the SBIR Phase II support

period, including details on any independent third-party investor and/or strategic partner funding that will or has already been secured. Full commercialization of the intervention/product/technology should be carried out with non-SBIR funds.

Since conducting a clinical trial needed to commercialize an intervention/product/technology may be capital-intensive, this FOA also aims to encourage business relationships between applicant SBCs and third-party investors/strategic partners who can provide substantial financing (co-funding) to help accelerate the commercialization of promising new interventions, products, and technologies initiated with NIH SBIR funding. In light of these goals, applicants are encouraged to promote and establish business relationships with investors and/or strategic partners that have appropriate prior experience in the commercialization of emerging biomedical technologies. The Commercialization Plan should include details on any co-funding, from public or private institutions that have already been secured or are anticipated.

Awards made under the NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44) FOA **will NOT provide support for:**

- clinical trial planning tasks, such as:
    - Development of study design
    - Identification of collaborators and enrollment sites
    - Development of the clinical protocol and informed consent form
    - Development of the statistical analysis plan
    - Development of the data management plan
    - Development of the Investigator’s brochure or equivalent
- clinical trials that fall outside the mission and goals of the NIAID;
- clinical trials that propose to use dedicated resources that are part of an existing NIAID-supported clinical trial network; or
- more than one proposed clinical trial per application (applicants should not propose more than one clinical trial within an application).

The NIAID reserves the right to specify: 1) whether an IND (Investigational New Drug)/IDE (Investigational Device Exemption) application should be submitted to an appropriate regulatory agency; 2) the entity (NIAID, primary awardee, etc.) who will hold the IND/IDE; and 3) the requirements for the establishment of a DSMB (Data Safety Monitoring Board)/SMC (Safety Monitoring Committee).

All research and development activities associated with awards made under this NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44) FOA must be performed within the United States.